

The Claims As Amended By The Present Requested Amendments:59
1317
1. (Once Amended)

A drug delivery and dilution device comprising:
an elongate body comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a passageway extending between the proximal and distal ends; and
a diffuser element operatively associated with the elongate body so as to define a diffusion space, wherein the diffusion space is in fluid communication with the elongate body passageway;
wherein a drug at a first concentration is introduced into the elongate body inlet, moves through the elongate body passageway, out the elongate body outlet, into the diffusion space, and substantially diffuses out through the diffuser element to exit the device such that the drug, upon delivery, is diluted to a second concentration that is less than the first concentration.

2. The device of claim 1, wherein the diffuser element is the diffuser element comprising a material selected from the group consisting of a semipermeable membrane, a microporous membrane and an ion exchange membrane.

3. The device of claim 1, wherein the elongate body and the diffuser element are operatively associated by attachment to a drug delivery device.

4. The device of claim 1, wherein the elongate body is defined by an exit orifice of a drug delivery device.

5. The device of claim 4, wherein the diffuser element is provided as a cap attached to a distal end of the drug delivery device.

6. The device of claim 1, wherein the diffusion space is defined by an outer wall of the elongate body and an inner wall of the diffuser element.

7. The device of claim 1, wherein said diffuser element envelops at least a portion of said elongate body.

8. The device of claim 1, wherein the diffuser element is microporous.

9. The device of claim 1, wherein the diffuser element is a dense membrane.

10. The device of claim 1, wherein the diffuser element is an ion-exchange membrane.

11. The device of claim 1, wherein said diffuser element distal end extends distally beyond the elongate body distal end.

12. The device of claim 1, wherein the diffuser element is ring-shaped element.

13. The device of claim 1, wherein the diffuser element is substantially impermeable to biological fluids or components of biological fluids.

14. The device of claim 1, wherein the diffuser element is selectively permeable to water.

15. The device of claim 1, wherein the device further comprises a dilutor element operatively associated with the elongate body so as to be in fluid communication with the elongate body passageway, the dilutor element comprising a selectively water permeable material to allow ingress of water for dilution of the formulation during transit through the device.

16. The device of claim 15, wherein the dilutor element comprises at least a portion of a wall of the diffuser element.

17. The device of claim 1, wherein the elongate body comprises at least two outlets.

18. The device of claim 1, wherein said elongate body defines at least two passageways.

19. The device of claim 1, wherein the elongate body passageway is adapted for delivery of agent at a low volume rate.

20. **(Once Amended)** A drug delivery system comprising:
the drug delivery and dilution device of claim 1, communicably attached to a drug-containing reservoir.

21. The drug delivery system of claim 20, wherein the drug delivery device is a convective drug delivery device.

22. The drug delivery system of claim 20, wherein said drug delivery device is implantable.

24. **(Once Amended)** The method of claim 25, wherein the formulation is introduced into the inlet at a low volume rate.

25. **(Once Amended)** A method for delivery of an agent to a delivery site in a subject, the method comprising the steps of:
implanting at least a distal portion of a local concentration management device according to claim 1 at a delivery site in a subject; and
introducing a formulation comprising an agent into the inlet of the elongate body;
wherein the introduced agent flows through the elongate body passageway and diffuses out the local concentration management device to the delivery site in the subject, wherein the elongate body passageway is at least partially filled with an agent formulation prior to said implanting.

26. **(Once Amended)** A method for diluting the concentration of an agent exiting a device, the method comprising:

implanting at least a distal portion of a local concentration management device according to claim 1 at a delivery site in a subject; and

introducing a formulation comprising an agent at a first concentration into the inlet of the elongate body;

wherein the introduced agent flows through the elongate body passageway, diffuses out the local concentration management device to the delivery site in the subject, and wherein the agent in the formulation is diluted to second concentration at the delivery site, the second agent concentration being less than the first agent concentration.

27. **(Once Amended)** A method for diluting the concentration of an agent exiting a device, the method comprising:

implanting at least a distal portion of a local concentration management device according to claim 1 at a delivery site in a subject; and

introducing a formulation comprising an agent at a first concentration into the inlet of the elongate body;

wherein the introduced agent flows through the elongate body passageway, diffuses out the local concentration management device to the delivery site in the subject, and wherein the agent in the formulation is diluted to second concentration prior to exit at the delivery site, the second agent concentration being less than the first agent concentration.

28. **(Cancel)** A method for dispersing a drug delivery stream, the method comprising:

implanting at least a distal portion of a local concentration management device according to claim 1 at a delivery site in a subject; and

introducing a formulation comprising an agent into the inlet of the elongate body; wherein the introduced agent flows through the elongate body passageway, out the local concentration management device and to the delivery site in the subject in a pattern that is disperse relative to a delivery pathway through the device , and wherein the agent in the formulation is diluted to second concentration at the delivery site, the second agent concentration being less than the first agent concentration.

29. (New) The device of claim 1 wherein the diffuser element comprises a polymeric film.

30. (New) The device of claim 29 wherein the diffuser element has a Diffusion Coefficient (DC) value in the range between 4.1×10^{-6} and 3.3×10^{-5} $\mu\text{g}/\text{cm}/\text{sec}$.

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